The opinion in support of the decision being entered today was <u>not</u> written for publication and is <u>not</u> binding precedent of the Board.

Paper No. 24

#### UNITED STATES PATENT AND TRADEMARK OFFICE

# BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

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Ex parte MICHAEL H. WIGLER and JOHN J. COLICELLI

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Application 08/471,884

HEARD: August 9, 2001

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Before WINTERS, MILLS, and GRIMES, <u>Administrative Patent Judges</u>. WINTERS, <u>Administrative Patent Judge</u>.

## **DECISION ON APPEAL**

In Paper No. 10 received September 17, 1997, applicants filed a notice of appeal from the examiner's decision finally rejecting claims 22 through 31, which are all of the claims remaining in the application. Subsequently, in Paper No. 22 received August 1, 2001, applicants proffered an amendment canceling claims 22 through 30. According to applicants, "claims 22-30 are cancelled in favor of the claims in US Patent No. 6,080,540 which issued on June 27, 2000 subsequent to briefing of the present appeal." We shall construe the proffered amendment as a withdrawal of the appeal of claims 22

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through 30. Accordingly, the appeal with respect to those claims is <u>dismissed</u>. This leaves claim 31 before us.<sup>1</sup>

#### THE APPEALED CLAIM

Claim 31 reads as follows:

- 31. (Amended) A method of identifying a chemical agent which alters activity of a protein encoded by a mammalian gene which, when expressed in genetically altered [yeast] <u>host</u> cells, modifies a phenotypic alteration associated with a genetic alteration in the [yeast] <u>host</u> cells, comprising the steps of :
  - (a) expressing the protein encoded by the mammalian gene in genetically altered [yeast] <u>host</u> cells in which the protein encoded by the mammalian gene is not expressed, thereby modifying the phenotypic alteration associated with the genetic alteration;
  - (b) obtaining from genetically altered [yeast] <u>host</u> cells produced in step (a) protein encoded by the mammalian gene;
  - (c) combining protein encoded by the mammalian gene with a chemical agent to be assayed for its ability to alter activity of the protein encoded by the mammalian gene; and
  - (d) determining activity of the protein encoded by the mammalian gene in combination with the chemical agent.

## THE REFERENCES

The prior art references relied on by the examiner are:

Goddard et al. (Goddard), "Cloning of human purine-nucleoside phosphorylase cDNA sequences by complementation in <u>Escherichia coli</u>." <u>Proceedings of the National Academy of Sciences</u>, USA, Vol. 80, pp. 4281-4285, July 1983

Kataoka et al. (Kataoka), "Functional cloning of mammalian and yeast RAS genes." Cell, Vol. 40 pp. 19-26, January 1985

Lee et al. (Lee), "Complementation used to clone a human homologue of the fission yeast cell cycle control gene cdc2," <u>Nature</u>, Vol. 327 pp. 31-35, May 1987

Chang et al. (Chang), "Phenotypic expression in <u>E. Coli</u> of a DNA sequence coding for mouse dihydrofolate reductase," Nature, Vol. 275 pp. 617-624, October 1978

<sup>&</sup>lt;sup>1</sup> On return of this application to the examining corps, we recommend that the examiner approve entry of the proffered amendment canceling claims 22 through 30.

# THE ISSUE

The sole issue on appeal is whether the examiner erred in rejecting claim 31 under 35 U.S.C. § 103 as unpatentable over the combined disclosures of Goddard, Kataoka, Lee, and Chang.

## **DELIBERATIONS**

Our deliberations in this matter have included evaluation and review of the following materials:

- (1) the instant specification, including Figures 1 through 8 and claim 31 on appeal;
  - (2) applicants' Appeal Brief (Paper No. 12) and the Reply Brief (Paper No. 17);
  - (3) the Examiner's Answer (Paper No. 13);
  - (4) the above-cited prior art references; and
  - (5) US Patent No. 6,080,540 issued June 27, 2000 to Wigler et al.

On consideration of the record, including the above-listed materials, we <u>reverse</u> the examiner's rejection under 35 U.S.C. § 103.

#### **DISCUSSION**

The pivotal reference in this case is Chang. Applicants argue, and the examiner does not deny, that the <u>E. coli</u> strain disclosed by Chang expresses bacterial dihydrofolate reductase (DHFR). <u>See</u> Chang, page 617, second paragraph. That is why Chang carries out the assay described at length in the Chang reference. The assay is needed to distinguish between bacterial DHFR and cloned mammalian DHFR.

In other words, for Chang, the expression of mammalian DHFR by a bacterial host (E. coli) and the assay are inextricably linked. If Chang's E. coli strain did not express DHFR, there would have been no need for Chang to carry out the disclosed assay. In view of the foregoing, we believe that the examiner's rejection under 35 U.S.C. § 103 is predicated on the impermissible use of hindsight. The examiner relies on Chang's disclosure to reach the assay steps recited in claim 31. Note, however, that the appealed claim also calls for "host cells in which the protein encoded by the mammalian gene is not expressed" (emphasis added). See claim 31, step (a). In our judgment, a fair interpretation of the Chang reference would not have led a person having ordinary skill in the art to the assay steps recited in claim 31 in combination with "host cells in which the protein encoded by the mammalian gene is not expressed" (emphasis added). Again, Chang's E. coli strain expresses bacterial DHFR and, for Chang, the expression of mammalian DHFR by a bacterial host and the assay are inextricably linked. Furthermore, the disclosures of Goddard, Kataoka, and Lee do not cure the above-noted deficiency in the disclosure of Chang. For this reason, we reverse the rejection of claim 31 under 35 U.S.C. § 103 as unpatentable over the combined disclosures of Goddard, Kataoka, Lee, and Chang.

One further matter warrants attention. At the oral hearing on August 9, 2001, counsel acknowledged that claim 31 on appeal and claim 10 in US Patent No. 6,080,540, issued June 27, 2000, are not patentably distinct.<sup>2</sup> Counsel further expressed a willingness to file a terminal disclaimer in this application. Accordingly, on return of this application to the examining corps, we recommend that the examiner:

<sup>&</sup>lt;sup>2</sup> At the oral hearing, Greta E. Noland (Registration No. 35,302) argued on behalf of the applicants.

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- (1) enter an obviousness type double patenting rejection of claim 31 over claim 10 of US Patent No. 6,080,540; and
- (2) require that applicants file a terminal disclaimer in this application in light of claim 10 of the '540 patent.

The examiner's decision is reversed.

# **REVERSED**

Sherman D. Winters Administrative Patent Judge	) ) )
Demetra J. Mills Administrative Patent Judge	) ) BOARD OF PATENT ) ) APPEALS AND
	) ) INTERFERENCES
Eric Grimes Administrative Patent Judge	) ) )

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